

Claims

What is claimed is:

1. An analytical device for determining the presence or amount of a
5 target ligand in a test sample, said device comprising: an array of structures,
wherein each said structure comprises a surface which comprises an immobilized
ligand receptor covalently or non-covalently attached thereto, said immobilized
ligand receptor capable of binding a target ligand; and, one or more channels,
whereby when test sample containing target ligand flows through said channel(s),
10 said target ligand diffuses across the width of said channel(s) and binds to said
immobilized reagent.
2. The device of claim 1 wherein the target ligand is an analyte, analyte
conjugate, analyte-analog, analyte-analog conjugate, ancillary binding member, or
15 labeled reagent.
3. The analytical device of claim 2 wherein said analyte is an antigen,
nucleotide sequence, lectin, or avidin and said immobilized reagent is selected from
the group consisting of antibody, complementary nucleotide sequence, carbohydrate
20 or biotin.
4. The analytical device of claim 1 wherein said structures are made
with copolymers, blends, laminates, metallized foils, metallized films or metals
deposited on a material selected from the group consisting of: polyolefins,
25 polyesters, styrene containing polymers, polycarbonate, acrylic polymers, chlorine
containing polymers, acetal homopolymers and copolymers, cellulose and their
esters, cellulose nitrate, fluorine containing polymers, polyamides, polyimides,
polymethylmethacrylates, sulfur containing polymers, polyurethanes, silicon
containing polymers, glass, silicone, and ceramic materials.
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5. The analytical device of claim 1 wherein said structures are made
with a plastic, elastomer, latex, silicon chip, or metal.

6. The analytical device of claim 5 wherein said structures are made with: TEFLON®, polystyrene, polyacrylate, polycarbonate, polyethylene, polypropylene, silicon elastomers, polystyrene latex or hydrophobic polymers.

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7. The analytical device of claim 6 wherein said structures are made with a hydrophobic polymer which comprises polypropylene, polyethylene, or polyester.

10 8. The analytical device of claim 1 wherein said structures are made with plastics which are capable of being milled or injection molded or from surfaces of copper, silver and gold films upon which are adsorbed various long chain alkanethiols.

15 9. The analytical device of claim 8 wherein said structures comprise a plastic which is capable of being milled or injection molded.

20 10. The analytical device of claim 1 wherein said structures are similarly shaped, said shapes selected from the group consisting of diamonds, hexagons, octagons, rectangles, squares, circles, semi-circles, triangles and ellipses.

11. The analytical device of claim 10 wherein said array of structures are staggered relative to the direction of test sample flow.

25 12. The analytical device of claim 1 wherein said array of structures have multiple immobilized ligand receptors permitting testing for multiple ligands in said test sample.

30 13. The analytical device of claim 1 further comprising a reservoir for the addition of the test sample, said reservoir comprising a plurality of pathways each of which leads to the array of structures, said pathways capable of transporting the test sample from said reservoir to said array.

14. An analytical device for determining a presence or amount of a ligand in a test sample, said device comprising: an inlet port and a vent; an array of structures, each structure having a surface providing an immobilized receptor covalently or non-covalently attached to said surface of said structure, said receptor capable of binding a ligand; one or more channel(s), whereby when said test sample containing a ligand flows through said channel(s), said ligand diffuses across the width of said channel(s) to bind said immobilized receptor; and, a labeled reagent comprising a specific binding member conjugated to a detectable label, said labeled reagent capable of producing a signal at said immobilized receptor to indicate the presence or amount of a ligand in a test sample.

15. The device of claim 14 wherein said ligand is an analyte, analyte conjugate, analyte-analog, analyte-analog conjugate, or ancillary binding member.

16. A method for determining the presence or amount of analyte in a test sample comprising: providing an analytical device comprising an inlet port, a vent, one or more channel(s), and an array of structures wherein each of said structures has immobilized receptor on at least one surface thereof, said receptor capable of binding a ligand; adding said test sample to said inlet port, said channel(s) transporting said test sample from said inlet port to said array of structures; said test sample entering said channel(s), said analyte diffusing through the width of said channel(s), whereby said sample contacts the array of structures comprising immobilized receptor, whereby analyte in said sample is bound by the immobilized receptor; and,

detecting said analyte through an analyte detection system comprising a specific binding member conjugated to a detectable label, said detectable label capable of producing a signal at said receptor-bound analyte, said detection determining the presence or amount of said analyte in said test sample.

17. The device of claim 16 wherein the ligand is an analyte, analyte-analog, ancillary binding member, or labeled reagent.

18. A method for determining the presence or amount of a ligand in a test sample, said method comprising:

5 providing an analytical device having an inlet port, a vent, and an array of structures comprising a plurality of channels, said structures of the array comprising immobilized to surfaces thereof receptors capable of binding a ligand or ligand analogue; placing said test sample in contact with said array of structures, whereby said receptors bind said ligand or ligand analogue in an amount corresponding to the presence of the ligand in the sample, and, detecting the presence of ligand in said test
10 sample by determining the amount of ligand or ligand analogue bound by the receptors.

19. The method of claim 18 wherein the placing step comprises placing said test sample in contact with said array of structures, whereby said receptors bind
15 said ligand or ligand analogue in an amount corresponding to the amount of the ligand in the sample.

20. A method of manufacturing analytical devices from a master, comprising providing a master having an array of structures having one or more
20 channels therebetween; and, preparing copies of the master.

21. A capillary space comprising a lumen which comprises at least one rectilinear angle when viewed in a cross section, said capillary space comprising a hydrophobic zone on a luminal surface thereof.

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22. The capillary space of claim 21, wherein the hydrophobic zone borders the angle.

23. The capillary space of claim 21, wherein the hydrophobic zone
30 substantially covers a surface adjacent the angle.

24. The capillary space of claim 21, wherein the hydrophobic zone covers 1% to 90% of a surface adjacent the angle.

25. The capillary space of claim 21, wherein the hydrophobic zone is adjacent to a hydrophilic surface.

26. A device comprising a capillary space of claim 21.

27. A material configured to fit into a capillary space, said material comprising a hydrophobic zone on a surface thereof.

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28. The material of claim 27, wherein the hydrophobic surface covers 1% to 90% of a surface of the material.

29. The material of claim 27, wherein the material comprises a filter, membrane or mesh.

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30. The material of claim 27, wherein the material is capable of fitting in a capillary space comprising at least one rectilinear angle, and the hydrophobic surface of the material is capable of being placed adjacent the angle of the capillary space.

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31. A material comprising a hydrophobic zone, whereby upon addition of liquid to the material said hydrophobic zone is capable of delimiting a discrete area of liquid on a surface of the material or within the material.

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32. The material of claim 31 wherein the material comprises a membrane.

33. The material of claim 31 wherein the material comprises a surface.

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34. The material of claim 33 wherein the surface comprises a means to facilitate capillary flow.

35. A zone comprising: a region capable of having a fluid placed thereon, and a hydrophobic region adjacent to the region capable of containing a fluid placed thereon, whereby the hydrophobic region impedes the flow of fluid into that hydrophobic region.

36. The zone of claim 35, where the region capable of containing a fluid placed thereon is a surface of a chamber which comprises at least one rectilinear angle when viewed along a cross section, and where the hydrophobic region is comprised within the chamber adjacent the angle of the chamber.

37. The zone of claim 35, where the region capable of having a fluid placed thereon further comprises a post substantially perpendicular to a floor of this region; said post defining a rectilinear angle between a surface of the post and the floor, said post comprising a hydrophobic surface adjacent the rectilinear angle.

38. A method to facilitate uniform drying of a liquid, said method comprising: providing a zone of claim 35; introducing liquid into the region capable of having a fluid placed thereon; and, drying said liquid.

39. The method of claim 38 comprising: providing a surface of a chamber which comprises at least one rectilinear angle when viewed along a cross section, the chamber comprising a hydrophobic region adjacent the angle of the chamber; introducing liquid into the chamber; and, drying said liquid, whereby the hydrophobic region in the chamber serves to prevent formation of a meniscus of the fluid at the angle, where formation of the meniscus would have impaired uniform drying.

40. A method for manufacturing a capillary space comprising a hydrophobic surface and a hydrophilic surface, said method comprising: applying a hydrophobic material to a hydrophilic surface that is capable of forming a lumenal surface of a capillary space; or, masking a region of a hydrophobic surface that is

capable of forming a luminal surface of a capillary space; applying a means for producing a hydrophilic surface to the hydrophobic surface, whereby areas of the hydrophobic surface which are nonmasked become hydrophilic areas, and removing the masking to expose a hydrophobic region adjacent the hydrophilic areas.

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41. An assay device comprising: a sample addition reservoir; a sample reaction barrier fluidly connected to said sample addition reservoir; a reaction chamber fluidly connected to said sample reaction barrier, said chamber having at least two fingers in walls thereof, wherein said barrier has a higher capillarity than said reaction chamber; a time gate fluidly connected to the reaction chamber, said time gate capable of permitting fluid to pass therethrough at a desired flow rate; a diagnostic element fluidly connected to the time gate, said diagnostic element capable of immobilizing at least one conjugate in at least one zone; and, a used reagent reservoir fluidly connected to said diagnostic element, whereby fluid can flow in sequence from said sample addition reservoir, to said barrier, to said reaction chamber, to said time gate, to said diagnostic element then to said used reagent reservoir.

42. The device of claim 41 wherein the sample addition reservoir comprises a filter capable of separating particulate matter from a fluid sample.

43. The device of claim 41 wherein the sample reaction barrier comprises a plurality of texture structures on a surface thereof, wherein said texture structures have a texture height of 0.01 to 0.02 mm, a width of 0.10 to 0.20 mm, and a distance between adjacent texture structures is 0.08 to 0.10 mm.

44. The device of claim 41 wherein the reaction barrier comprises a capillary space having a height of about 0.03 to 0.07 mm.

45. The device of claim 41 wherein the reaction barrier comprises a corner, and comprises a hydrophobic zone at said corner.

46. The device of claim 41 wherein the reaction barrier comprises 10 vertical grooves, wherein each said groove is about 0.02 to 0.03 mm high, and each said groove is spaced about 0.5 to 1.5 mm apart.

5 47. The device of claim 41 wherein the reaction chamber comprises a capillary space about 0.03 to 1.0 mm high and a volume of about 0.2 to 6 μ l.

48. The device of claim 41 wherein the reaction chamber comprises a plurality of texture structures, wherein each of said texture structures are posts about 10 0.015 to 0.03 mm high, with a diameter of about 0.05 to 0.1 mm, and wherein adjacent posts are spaced about 0.015 to 0.025 mm apart.

49. The device of claim 41 wherein the reaction chamber comprises a plurality of grooves oriented perpendicular to a predominant direction of fluid flow, 15 wherein each of said grooves is about 0.03 to 0.07 mm high, and adjacent grooves are about 0.08 to 0.12 mm apart.

50. The device of claim 41 wherein the reaction chamber comprises an edge or corner, and comprises a hydrophobic zone at said edge or corner. 20

51. The device of claim 41 wherein the time gate comprises a height of about 0.02 to 0.12 mm, and a plurality of grooves oriented perpendicular to a predominant direction of fluid flow, wherein each of said grooves is about 0.03 to 0.07 mm high and adjacent grooves are about 0.08 to 0.12 mm apart. 25

52. The device of claim 41 wherein the diagnostic element comprises a height of about 0.01 to 0.05 mm, a volume of about 0.5 to 3 μ l.

53. The device of claim 41 wherein the diagnostic element comprises a plurality of texture structures, wherein each of said texture structures is about 0.01 to 0.02 mm high, a diameter of about 0.03 to 0.07 mm, and adjacent texture structures are about 0.04 to 0.09 mm apart. 30

54. The device of claim 41 wherein the diagnostic element comprises an edge or corner, and comprises a hydrophobic zone at said edge or corner.

5 55. The device of claim 41 wherein the used reagent reservoir comprises a height of about 0.01 to 0.05 mm, a volume of greater than about 1 μ l.

56. The device of claim 41 wherein the used reagent reservoir comprises a plurality of texture structures, wherein each said texture structure comprises a
10 height of 0.01 to 0.02 mm, a diameter of 0.03 to 0.07 mm, and wherein adjacent texture structures are about 0.04 to 0.09 mm apart.

57. The device of claim 41 further comprising a dead space region positioned between a surface of the diagnostic element and a surface of the used
15 reagent reservoir.

58. A device capable of performing an assay, said device comprising two or more surfaces that are contacted by fluid during performance of the assay, wherein a first fluid-contacting device surface comprises a first immunoassay reagent immobilized thereon and a second fluid-contacting device surface comprises
20 a second immunoassay reagent immobilized thereon.

59. The device of claim 58 wherein said device comprises a capillary space through which a fluid to be assayed flows during performance of the assay, said capillary space comprising two or more fluid-contacting surfaces, wherein a
25 first fluid-contacting surface of the capillary space comprises a first immunoassay reagent immobilized thereon and a second fluid-contacting surface of the capillary space comprises a second immunoassay reagent immobilized thereon.

60. The device of claim 58 further comprising that the first immunoassay
30 reagent is diffusibly immobilized on the first fluid-contacting surface, the second immunoassay reagent is diffusibly immobilized on the second fluid-contacting

surface or each immunoassay reagent is diffusibly immobilized on each fluid-contacting surface.

5 61. The device of claim 58 wherein the first immunoassay reagent is nondiffusibly immobilized on the first fluid-contacting surface, the second immunoassay reagent is nondiffusibly immobilized on the second fluid-contacting surface, or each immunoassay reagents are nondiffusibly immobilized on each fluid-contacting surface.

10 62. The device of claim 58 wherein the capillary space comprises a third fluid-contacting surface wherein said third capillary space surface comprises a third immunoassay reagent immobilized thereon.

15 63. The device of claim 62 wherein the third immunoassay reagent is diffusibly immobilized on the third fluid-contacting surface or the third immunoassay reagent is nondiffusibly immobilized on the third fluid-contacting surface.

20 64. The device of claim 58 wherein the capillary space further comprises a particle comprising an immunoassay reagent immobilized thereon.

25 65. A device capable of performing an assay, said device comprising a stop and an energy director, whereby during manufacture of the device the energy director serves to seal a first device piece to a second device piece and to define a capillary space in the device, and the stop serves to allow preparation of a device chamber with uniform dimensions.

30 66. The device of claim 65 wherein the stop and the energy director comprise a unitary structure.

 67. The device of claim 65 wherein the stop and the energy director delimit a dead space of the device into which a fluid is incapable of flowing.

68. The device of claim 65 wherein the stop comprises a post or a ridge.

69. The device of claim 65 wherein the energy director comprises a post
5 or a ridge.

70. A surface configured to facilitate placement of a uniform layer of
dried reagent thereon, said surface comprising a plurality of texture structures,
whereby a plurality of menisci are formed when a fluid is placed in contact with the
surface.

71. A device capable of performing an assay comprising a surface of
claim 70.

72. A method for placing a uniform layer of dried reagent on a surface,
15 said method comprising: providing a surface of claim 70; placing a fluid in contact
with the surface; and, drying the fluid.

73. The method of claim 72 wherein the drying step comprises waiting a
period of time for evaporation to occur or application of an external energy source to
20 facilitate evaporation.